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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,801	07/11/2006	Tomizo Yamamoto	2006-0936A	9829

513 7590 05/20/2010  
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Washington, DC 20005-1503

EXAMINER
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KARPINSKI, LUKE E

ART UNIT	PAPER NUMBER
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1616

NOTIFICATION DATE	DELIVERY MODE
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05/20/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ddalecki@wenderoth.com  
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<b>Office Action Summary</b>	<b>Application No.</b> 10/582,801	<b>Applicant(s)</b> YAMAMOTO, TOMIZO	
	<b>Examiner</b> LUKE E. KARPINSKI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/12/2010</u> .   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Receipt of amendments, arguments, and remarks filed 2/12/2010 is acknowledged.

#### ***Claims***

Claim 14 is canceled.

Claims 1-13 and 15-18 are pending.

Claims 1, 2, 6, 10-13, and 15-17 are amended.

Claim 18 is new and withdrawn.

Claims 1-13 and 15-17 are under consideration in this action.

#### ***Election by Original Presentation***

Claim 18 is restricted by original presentation. All original claims are drawn to an activated foam product, newly added claim 18 is drawn to a method of increasing the efficacy of a pharmaceutical agent. Said inventions are not linked under 371 rules due to the fact that there is no common special technical feature as evidenced by the rejection of record.

#### ***Rejections***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or

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newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 are indefinite for reciting the term 'directly or indirectly'. Either said foam is in contact with a body or is not in contact with a body.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.

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3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**1. Claims 1-13, 15-17 are rejected under 35 U.S.C. 103(a)** as being unpatentable over US Patent 6,455,610 to Lever et al. in view of US Patent 3,644,235 to Gray and US Patent 7,056,883 to Ito et al.

### ***Applicant Claims***

Applicant claims a closed-cell foam rubber comprising a rubber or resin, zirconium and/or germanium, and carbon, wherein said foam is in contact with a human when a pharmaceutical is administered.

Applicant further claims specific pharmaceuticals and foam densities.

### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Lever et al. teach rubber compositions comprising zirconium (col. 5, lines 57-67 and examples), carbon (col. 3, lines 63-67 and examples), a closed cell foam structure (col. 4, lines 36-49), and that said rubbers may be utilized to make articles which would be in contact with a human body (col. 9, lines 1-12), as pertaining to claims 1 and 2.

Lever et al. further teach said compositions comprising a blowing agent (col. 4, lines 44-49), as pertaining to claims 6 and 10-17.

***Ascertainment of the Difference between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

Lever et al. do not teach densities of said foam rubbers as claimed in claims 6 and 10-17. This deficiency in Lever et al. is cured by Gray. Gray teaches foam compositions and that the density of said compositions may be altered by using different proportions of blowing agents (col. 4, lines 30-32).

Further, Lever et al. do not teach pharmaceuticals as claimed in claims 1-5, and 7-9. This deficiency is cured by Ito et al. Ito et al. teach histone deacetylase inhibitors (abstract) for topical administration (col. 5, lines 35-44).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

Regarding claims 6 and 10-17, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to produce the rubber formulations of Lever et al. with a density of 20-30 cells per square millimeter as taught by Gray in order to produce the invention of instant claims 6 and 10-17.

One of ordinary skill in the art would have been motivated to do this because Lever et al. teaches rubber articles comprising a blowing agent and Gray teaches that by altering the percentage of blowing agent one may alter the foam density, therefore one of ordinary skill in the art would have been well aware that the articles of Lever et al. could be produced with different densities simply by altering the blowing agent percentage and one of skill would have been capable of altering said foams to contain 20-30 cells per square millimeter. Therefore it would have been obvious to utilize

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density modifying technique of Gray, with the formulations of Lever et al. in order to produce articles of different densities.

Regarding claims 1-5 and 7-9, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have a human body in contact with said foams when a pharmaceutical is administered in order to produce the invention of instant claims 1-5 and 7-9.

One of ordinary skill in the art would have been motivated to do this because lever et al. teach that said foams may be utilized to make clothing and Ito et al. teach that HDACI is a pharmaceutical administered to treat cancer. Therefore it would have been obvious that when said pharmaceuticals were administered one could be wearing a shirt made of said foams.

Further regarding claims 1-5 and 7-9, said claims are product claims NOT method claims. The fact that applicant claims said foams are in contact with a human when a pharmaceutical is administered is of no consequence and bears no patentable weight. Also there appears to be no connection between said foams and said pharmaceuticals at all, said foams do not contain said pharmaceutical, are not in contact with said drug, and are not claimed to affect said drug in any way. Regardless, the examiner has provided art showing that said foams are well known as are said pharmaceuticals. The examiner suggests amending said claims to proper form, wherein either a product or a method is claimed, not a hybrid of the two.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed

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invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

### ***Response to Arguments***

Applicant's arguments filed 2/12/2010 have been fully considered but they are not persuasive.

Applicant argues that Lever et al. is not directed to the use of activated foam with the aim of enhancing a drug.

Lever et al. is not required to teach any such aim. Lever et al. teach the same foams as claimed, the limitation of said foam being in contact with a human body when a pharmaceutical is administered is an intended use and given no patentable weight.

Applicant also argues that Lever et al. do not require a closed cell foam.

This argument is not found persuasive because Lever et al. teach closed cell foam (col. 4, line 47).

Applicants also argue that Ito et al. do not describe a drug used with said foam.

This argument is not found persuasive because the instant claims are to a foam product, as stated by applicant in the response filed 2/12/2010 said foam and said drug are not incorporated into the same composition and there are no method claims.

Applicant's claims are drawn to a foam material and to a drug, there is no requirement to show any correlation between the two due to said claims being drawn to a product. If



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applicant desires claims to the use of said foam with a drug the examiner suggests the pursuit of method claims.

### ***Conclusion***

Claim 18 is withdrawn.

Claims 1-13 and 15-17 are rejected.

Claim 14 is cancelled.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LUKE E. KARPINSKI whose telephone number is (571)270-3501. The examiner can normally be reached on Monday Friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEK

*/Mina Haghighatian/*  
Primary Examiner, Art Unit 1616